

REMARKS/ARGUMENTS

Claims 13-16, 18-26, and 74 are currently pending and stand substantively rejected. This Amendment cancels claims 16 and 23, adds new claims 76-82, and amends claims 13-15, 25, and 26. The paragraph numbering below follows that of the Office Action. Applicants representative thanks the Examiner for the courtesies extended during a telephone conversation of March 15, 2007.

New and Amended Claims

Support for elements of the new and amended claims can be found in the specification as follows. No new matter is introduced.

Support for **hybridoma:**

Support for the claimed hybridoma can be found in the specification at, for example, page 11, lines 4-9 (as amended by the Preliminary Amendment filed July 9, 2004).

Support for **binding and **assay**:**

Fig. 8, which is discussed in the specification at, for example, page 7 lines 7-8, shows the binding of MAb 763-15-5 to allelic variants 2C9*1, 2C9*2, and 2C9*3. At page 7, lines 14-15, the specification describes specific binding as a binding affinity of at least 10^6 M⁻¹. The ELISA assay is discussed in the specification at, for example, page 27, lines 3-6 (as amended by the Amendment filed October 24, 2006).

Support for **competition:**

Support for this element can be found in the specification at, for example, page 11, lines 16-30, and page 14, lines 19-22.

Support for **phenanthrene metabolism:**

Fig. 2, which is discussed in the specification at, for example, page 6, lines 23-25 and page 26, lines 4-12, shows the inhibitory activity of MAb 763-15-5 toward 2C9*1 and 2C9*2 catalyzed metabolism of phenanthrene.

Support for **diclofenac metabolism:**

Fig. 9, which is discussed in the specification at, for example, page 7, lines 9-10 and page 27, lines 6-11, as well as Fig. 11, which is discussed in the specification at, for

example, page 7, line 12 and page 27, lines 17-20, each show the inhibitory activity of MAb 763-15-5 toward 2C9*1, 2C9*2, and 2C9*3 catalyzed metabolism of diclofenac.

¶7. First Rejection Under 35 U.S.C. §112

Claims 13-16, 18-26, and 74 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description in the specification. This rejection is traversed.

According to MPEP 2163.02 whenever the written description requirement issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. Applicants submit that the claims as set forth above in the Listing of Claims meet this test.

Amended claim 13 is drawn to a monoclonal antibody that inhibits 2C9*1 catalyzed metabolism of phenanthrene by at least 50% and 2C9*2 catalyzed metabolism of phenanthrene by at least 50%. As noted above, support for these elements can be found in the specification at, for example, Fig. 2, page 6 lines 23-25, and page 26, lines 4-12.

With regard to the inhibitory activity of MAb 763-15-5 toward 2C9*1 and 2C9*2 catalyzed metabolism of phenanthrene, Applicants submit the artisan would recognize that, based on the originally filed disclosure, the Applicants were in possession of the subject matter as set forth above in the Listing of Claims.

¶8. Second Rejection Under 35 U.S.C. §112

Claims 13-16, 18-26, and 74 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. This rejection is traversed.

According to MPEP 2171, the test for definiteness is based on whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art. The issues raised in the Office Action are addressed as follows.

A. As amended, claims 13, 15, 25, and 26 do not recite the element of specific inhibition.

B. Claim 16 is canceled.

C. Amended claims 13 and 25 recite the inhibitory activity in terms of each allele.

D. As amended, claim 13 indicates that the monoclonal antibody is produced by a hybridoma cell line.

Applicants submit that the scope of the claims as set forth above in the Listing of Claims would be clear to the hypothetical artisan, and therefore meet the test for definiteness. Withdrawal of this rejection is respectfully requested.

¶9. Third Rejection Under 35 U.S.C. §112

Claim 23 was rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. This rejection is traversed. Claim 23 is canceled. Withdrawal of this rejection is respectfully requested.

¶10. Fourth Rejection Under 35 U.S.C. §112

Claims 13-16, 18-26, and 74 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. This rejection is traversed.

According to MPEP 2164, the test for enablement involves whether the specification describes how to make and how to use the invention as claimed. Applicants submit that the claims as set forth above in the Listing of Claims meet this test.

Amended claim 13 is drawn to a monoclonal antibody that specifically binds to 2C9*1, 2C9*2, and 2C9*3, and that inhibits 2C9*1 and 2C9*2 catalyzed metabolism of phenanthrene. With regard to the inhibitory activity of MAb 763-15-5 toward 2C9*1 and 2C9*2 catalyzed metabolism of phenanthrene, Applicants submit the specification describes how to make and how to use the subject matter as set forth above in the Listing of Claims. Withdrawal of this rejection is respectfully requested.

¶11. Fifth Rejection Under 35 U.S.C. §112

Claim 23 was rejected under 35 U.S.C. §112, first paragraph, as allegedly not meeting the written description requirement. This rejection is traversed. Claim 23 is canceled. Withdrawal of this rejection is respectfully requested.

¶12. Sixth Rejection Under 35 U.S.C. §112

Claims 13-16, 18-26, and 74 were rejected under 35 U.S.C. §112, first paragraph, as allegedly not meeting the written description requirement. This rejection is traversed.

According to MPEP 2163(I), the written description test involves whether the specification describes the claimed subject matter in sufficient detail that the artisan can reasonably conclude that the inventor had possession of the claimed subject matter. Applicants submit that the claims as set forth above in the Listing of Claims meet this test.

Claim 13 is drawn to a monoclonal antibody that specifically binds to 2C9*1, 2C9*2, and 2C9*3, and that inhibits 2C9*1 and 2C9*2 catalyzed metabolism of phenanthrene.

With regard to the binding activity of MAb 763-15-5 and the inhibitory activity of MAb 763-15-5 toward 2C9*1 and 2C9*2 catalyzed metabolism of phenanthrene, Applicants submit the specification describes the claimed subject matter in sufficient detail that the artisan can reasonably conclude that the inventor had possession of the claimed subject matter. Withdrawal of this rejection is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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